DT03 Rec'd PCT/PT0 2 8 SEP 2004

10/509449

Practitioner's Docket No. <u>82310</u>

CHAPTER II

Preliminary Classification:

Proposed Class:

Subclass:

NOTE: "All applicants are requested to include a preliminary classification on newly filed patent applications. The preliminary classification, preferably class and subclass designations, should be identified in the upper right-hand corner of the letter of transmittal accompanying the application papers, for example 'Proposed Class 2, subclass 129.' " M.P.E.P., § 601, 7th ed.

TRANSMITTAL LETTER TO THE UNITED STATES ELECTED OFFICE (EO/US) (ENTRY INTO U.S. NATIONAL PHASE UNDER CHAPTER II)

PCT/EP03/03288

28 MARCH 2003

INTERNATIONAL APPLICATION NO.

INTERNATIONAL FILING DATE

PRIORITY DATE CLAIMED

METHODS AND COMPUTER PROGRAM PRODUCTS FOR THE QUALITY CONTROL TITLE OF INVENTION

OF NUCLEIC ACID ASSAYS

/ KPPY/GANT/SY

INVENTORS: PETER ADORJAN, FABIAN MODEL, THOMAS KOENIG,

CHRISTIAN PIEPENBROCK, KLAUS JUENEMANN, MATTHIAS BURGER AND SUSANNE SCHWENKE

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

EXPRESS MAILING UNDER 37 C.F.R. § 1.10*

(Express Mail label number is mandatory.) (Express Mail certification is optional.)

I hereby certify that this paper, along with any document referred to, is being deposited with the United States Postal Service on this date <u>Sept. 28, 2004</u> __, in an envelope addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 as "Express Mail Post Office to Addressee" Mailing Label No. EV 2 2 5 3 1 7 7 3 5 US

EDWARD M. KRIEGSMAN

(type or print name of person mailing paper)

Signature of person certifying

WARNING: Certificate of mailing (first class) or facsimile transmission procedures of 37 C.F.R. 1.8 cannot be used to obtain a date of mailing or transmission for this correspondence.

*WARNING: Each paper or fee filed by "Express Mail" must have the number of the "Express Mail" mailing label placed thereon prior to mailing. 37 C.F.R. 1.10(b).

> "Since the filing of correspondence under § 1.10 without the Express Mail mailing label thereon is an oversight that can be avoided by the exercise of reasonable care, requests for waiver of this requirement will not be granted on petition." Notice of Oct. 24, 1996, 60 Fed. Reg. 56,439, at 56,442.

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- NOTE: To avoid abandonment of the application, the applicant shall furnish to the USPTO, not later than the expiration of 30 months from the priority date: (1) a copy of the international application, unless it has been previously communicated by the International Bureau or unless it was originally filed in the USPTO; and (2) the basic national fee (see 37 C.F.R. § 1.492(a)). The 30-month time limit may not be extended. 37 C.F.R. § 1.495(a) and (b).
- WARNING: Where the items are those which can be submitted to complete the entry of the international application into the national phase are subsequent to 30 months from the priority date the application is still considered to be in the international state and if mailing procedures are utilized to obtain a date the express mail procedure of 37 C.F.R. § 1.10 must be used (since international application papers are not covered by an ordinary certificate of mailing—See 37 C.F.R. § 1.8.
- NOTE: Documents and fees must be clearly identified as a submission to enter the national state under 35 U.S.C. § 371 otherwise the submission will be considered as being made under 35 U.S.C. § 111. 37 C.F.R. § 1.494(g).
- I. Applicant herewith submits to the United States Elected Office (EO/US) the following items under 35 U.S.C. § 371:
 - a.

 This express request to immediately begin national examination procedures (35 U.S.C. § 371(f)).
 - b. Mational Fee (35 U.S.C. § 371(c)(1)) and other fees (37 C.F.R. § 1.492) as indicated below:

2. Fees

CLAIMS FEE	(1) FOR	(2) NUMBER FILED	(3) NUMBER EXTRA	(4) RATE	(5) CALCULA- TIONS
⊠*	TOTAL CLAIMS				
1		54 -20=	34	× \$18.00=	\$ 612
	INDEPENDENT CLAIMS				
		2 -3=	0	× \$86.00=	0
	MULTIPLE DEPE	ENDENT CLAIM(S) (if	applicable)	+ \$290.00	\$290
SMALL ENTITY					\$920 = \$1822 -,\$911 \$911
ļ		the enclosed assig	nment document	\$40.00 (37	911
	COVER SHEET".	(See Item 13 below)	. See aπached "A	SSIGNMENT	
TOTAL			Total	Fees enclosed	\$

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*See attac	ched Preliminary Amendment Reducing the Number of Claims.					
⊠ A	Attached is a ⊠ check ☐ money order in the amount of \$911					
	Authorization is hereby made to charge the amount of \$					
	to Deposit Account No.					
	to Credit card as shown on the attached credit card information authorization form PTO-2038.					
WARNING:	Credit card information should not be included on this form as it may become public.					
	Charge any additional fees required by this paper or credit any overpayment in the manner authorized above.					
A du	olicate of this paper is attached.					
"WARNING:	"To avoid abandonment of the application the applicant shall furnish to the United States Patent and Trademark Office not later than the expiration of 30 months from the priority date: " * * (2) the basic national fee (see § 1.492(a)). The 30-month time limit may not be extended." 37 C.F.R. § 1.495(b).					
WARNING:	If the translation of the international application and/or the oath or declaration have not been submitted by the applicant within thirty (30) months from the priority date, such requirements may be met within a time period set by the Office. 37 C.F.R. § 1.495(b)(2). The payment of the surcharge set forth in § 1.492(e) is required as a condition for accepting the oath or declaration later than thirty (30) months after the priority date. The payment of the processing fee set forth in § 1.492(f) is required for acceptance of an English translation later than thirty (30) months after the priority date. Failure to comply with these requirements will result in abandonment of the application. The provisions of § 1.136 apply to the period which is set. Notice of Jan. 3, 1993, 1147 O.G. 29 to 40.					

Applicant hereby asserts status as a small entity under 37 C.F.R. § 1.27.

NOTE: 37 C.F.R. § 1.27(c) deals with the assertion of small entity status, whether by a written specific declaration thereof or by payment as a small entity of the basic filing fee or the fee for the entry into the national phase as states:

"(c) Assertion of small entity status. Any party (person, small business concern or nonprofit organization) should make a determination, pursuant to paragraph (f) of this section, of entitlement to be accorded small entity status based on the definitions set forth in paragraph (a) of this section, and must, in order to establish small entity status for the purpose of paying small entity fees, actually make an assertion of entitlement to small entity status, in the manner set forth in paragraphs (c)(1) or (c)(3) of this section, in the application or patent in which such small entity fees are to be paid.

- (1) Assertion by writing. Small entity status may be established by a written assertion of entitlement to small entity status. A written assertion must:
 - (i) Be clearly identifiable;
 - (ii) Be signed (see paragraph (c)(2) of this section); and
 - (iii) Convey the concept of entitlement to small entity status, such as by stating that applicant is a small entity, or that small entity status is entitled to be asserted for the application or patent. While no specific words or wording are required to assert small entity status, the intent to assert small entity status must be clearly indicated in order to comply with the assertion requirement.
- (2) Parties who can sign and file the written assertion. The written assertion can be signed by;
 - (i) One of the parties identified in §§ 1.33(b) (e.g., an attorney or agent registered with the Office), §§ 3.73(b) of this chapter notwithstanding, who can also file the written assertion;
 - (ii) At least one of the individuals identified as an inventor (even though a §§ 1.63 executed oath or declaration has not been submitted), notwithstanding §§ 1.33(b)(4), who can also file the written assertion pursuant to the exception under §§ 1.33(b) of this part; or
 - (iii) An assignee of an undivided part interest, notwithstanding §§ 1.33(b)(3) and 3.73(b) of this chapter, but the partial assignee cannot file the assertion without resort to a party identified under §§ 1.33(b) of this part.

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(3) Assertion by payment of the small entity basic filing or basic national fee. The payment, by any party, of the exact amount of one of the small entity basic filing fees set forth in §§ 1.16(a), (f), (g), (h), or (k), or one of the small entity basic national fees set forth in §§ 1.492(a)(1), (a)(2), (a)(3), (a)(4), or (a)(5), will be treated as a written assertion of entitlement to small entity status even if the type of basic filing or basic national fee is inadvertently selected in error.

(i) If the Office accords small entity status based on payment of a small entity basic filing or basic national fee under paragraph (c)(3) of this section that is not applicable to that application, any balance of the small entity fee that is applicable to that application will be due along with the appropriate surcharge set forth in §§ 1.16(e), or §§ 1.16(f).

(ii) The payment of any small entity fee other than those set forth in paragraph (c)(3) of this section (whether in the exact fee amount or not) will not be treated as a written assertion of entitlement to small entity status and will not be sufficient to establish small entity status in an application or a patent."

3. A copy of the International application as filed (35 U.S.C. § 371(c)(2)):

NOTE: Section 1.495(b) requires that the basic national fee and a copy of the international application must be filed with the Office before the expiration of 30 months from the priority date to avoid abandonment. "The International Bureau normally provides the copy of the international application to the Office in accordance with PCT Article 20. At the same time, the International Bureau notifies applicant of the communication to the Office. In accordance with PCT Rule 47.1, that notice shall be accepted by all designated offices as conclusive evidence that the communication has duly taken place. Thus, if the applicant desires to enter the national stage, the applicant normally need only check to be sure the notice from the International Bureau has been received and then pay the basic national fee by 30 months from the priority date." Notice of Jan. 7, 1993, 1147 O.G. 29 to 40, at 35-36. See item 14c below.

		a.	X	is transmitted herewith.
		b.		is not required, as the application was filed with the United States Receiving Office.
		c.		has been transmitted
			i.	☐ by the International Bureau.
				Date of mailing of the application (from form PCT/1B/308):
			ii.	□ by applicant on (Date)
4.	A translation of the International application into the English languag (35 U.S.C. § 371(c)(2)):		• • • • • • • • • • • • • • • • • • • •	
		a.		is transmitted herewith.
		b.	X	is not required as the application was filed in English.
		c.		was previously transmitted by applicant on (Date)
		d.		will follow.

NOTE: 37 C.F.R. § 1.495(c): "If applicant complies with paragraph (b) of this section before expiration of thirty months from the priority date but omits . . . a translation of the international application, as filed, into the English language, if it was originally filed in another language (35 U.S.C. 371(c)(2)) . . . applicant will be so notified and given a period of time within which to file the translation . . . in order to prevent abandonment of the application. The payment of the processing fee set forth in § 1.492(f) is required for acceptance of an English translation later than the expiration of thirty months after the priority date A 'Sequence Listing' need not be translated if the 'Sequence Listing' complies with PCT Rule 12.1(d) and the description complies with PCT Rule 5.2(b)."

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5.	X				ments to the claims of the international application under PC1 Article 19 is.C. § 371(c)(3)):			
NOTE	a e n a	The Notice of January 7, 1993 points out that 37 C.F.R. § 1.495(d) requires that PCT Article 19 amendments must be submitted by 30 months from the priority date and this deadline may not be extended. The Notice further advises that: "The failure to do so will not result in loss of the subject matter of the PCT Article 19 amendments. Applicant may submit that subject matter in a preliminary amendment filed under section 1.121. In many cases, filing an amendment under section 1.121 is preferable since grammatical or idiomatic errors may be corrected." 1147 O.G. 29-40, at 36.						
NOTE	ti n w	rans ot la vhic	latioi ater i	n of than e no	those the c t rece	(d): "A copy of any amendments to the claims made under PCT Article 19, and a amendments into English, if they were made in another language, must be furnished expiration of thirty months from the prority date. Amendments under PCT Article 19 elived by the expiration of thirty months from the priority date will be considered to		
		a.	. [are	transmitted herewith.		
		b	. [hav	e been transmitted		
			i.			by the International Bureau.		
						Date of mailing of the amendment (from form PCT/1B/308):		
			i	i.		by applicant on (Date)		
		C.	. [Z	hav	e not been transmitted as		
			i.	•	×	applicant chose not to make amendments under PCT Article 19. Date of mailing of Search Report (from form PCT/ISA/210.): March 10, 2004		
			ii	i.		the time limit for the submission of amendments has not yet expired. The amendments or a statement that amendments have not been made will be transmitted before the expiration of the time limit under PCT Rule 46.1.		
6. ☑ A translation of the (38 U.S.C. § 371(c			of the amendments to the claims under PCT Article 19 371(c)(3)):					
		a.	. []	is tr	ansmitted herewith.		
		b.	. [is no	ot required as the amendments were made in the English language.		
		C.	. [2	X	has	not been transmitted for reasons indicated at point 5(c) above.		
7.		Α	CO	ру	of th	e international examination report (PCT/IPEA/409)		
					is tr	ansmitted herewith.		
						ot required as the application was filed with the United States eiving Office.		
8.		Α	nne	ex(es) to the international preliminary examination report				
		a.	. [is/aı	re transmitted herewith.		
		b.	. [_		re not required as the application was filed with the United States elving Office.		

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9.)	A t	ransl	ation of the annexes to the international preliminary examination repor
NOT		rep the by to	oort e exp the c para	(if app piration expira graph	1.497(e) "A translation into English of any annexes to an international preliminary examinatio blicable), if the annexes were made in another language, must be furnished not later that in of thirty months from the priority date. Translations of the annexes which are not receive tion of thirty months from the priority date may be submitted within any period set pursuar (c) of this section accompanied by the processing fee set forth in § 1.492(f). Annexes for ations are not timely received will be considered canceled."
			a.		is transmitted herewith.
			b.		is not required as the annexes are in the English language.
10.	10. ☑ An oath or declaration of the inventor (35 U.S.C. § 371(c)(4)) complying with 35 U.S.C. § 115				
			a.		was previously submitted by applicant on (Date
			b.		is submitted herewith, and such oath or declaration
				i.	is attached to the application.
				ii.	identifies the application and any amendments under PCT Articles 19 that were transmitted as stated in points 3(b) or 3(c) and 5(b) and states that they were reviewed by the inventor as required be 37 C.F.R. § 1.70.

c. X will follow.

NOTE: 37 C.F.R. § 1.495(c): "If applicant complies with paragraph (b) of this section before expiration of thirty months from the priority date but omits . . . the oath or declaration of the inventor (35 U.S.C. 371(c)(4) and § 1.497), if a declaration of inventorship in compliance with § 1.497 has not been previously submitted in the international application under PCT Rule 4.17(iv) within the time limits provided for in PCT Rule 26ter.1, applicant will be so notified and given a period of time within which to file the . . . oath or declaration in order to prevent abandonment of the application. . . . The payment of the surcharge set forth in § 1.492(e) is required for acceptance of the oath or declaration of the inventor later than the expiration of thirty months after the priority date."

II. Other document(s) or information included:

11. ☑ An International Search Report (PCT/ISA/210) or Declaration under PCT Article 17(2)(a):

WARNING: M.P.E.P., § 1893.03(g), 8th Edition: Information Disclosure Statement in a National Stage Application

"When an international application is filed under the Patent Cooperation Treaty (PCT), prior art documents may be cited by the examiner in the international search report and/or the international preliminary examination report. When a national stage application is filed under 35 U.S.C. 371, or a national application is filed under 35 U.S.C. 111 claiming benefit of the filing date of the international application, it is often desirable to have the examiner consider the documents cited in the international application when examining the national application.

"As a result of an agreement among the European Patent Office (EPO), Japanese Patent Office (JPO), and the United States Patent and Trademark Office (USPTO), copies of documents cited in the international search report issued by any one of these International Searching Authority Offices generally are being sent to the other Offices when designated in the international application. Accordingly, in many national stage applications where the international search was conducted by the EPO, JPO, or USPTO, copies of the documents cited in the international search report are made available to the examiner in the national stage application.

"When all the requirements for a national stage application have been completed, applicant is notified (Form PCT/DO/EO/903) of the acceptance of the application under 35 U.S.C. 371, including an itemized list of the items received. The itemized list includes an indication of whether a copy of the international search report and copies of the references cited therein are present in the national stage file. The examiner will consider the documents cited in the international search report, without any further action by applicant under 37 CFR 1.97 and 1.98, when both the international search report and copies of the documents are indicated to be present in the national stage file. The examiner will note the consideration in the first Office action. There is no requirement that the examiners list the documents on a PTO-892 form. See form paragraphs 6.53, 6.54, and 6.55 (reproduced in MPEP § 609). Otherwise, applicant must follow the procedure set forth in 37 CFR 1.97 and 1.98 in order to ensure that the examiner considers the documents cited in the international search report.

"This practice applies only to documents cited in the international search report relative to a national stage application filed under 35 U.S.C. 371. It does not apply to documents cited in an international preliminary examination report that are not cited in the search report. It does not apply to applications filed under 35 U.S.C. 111(a) claiming the benefit of an international application filing date."

	a.	\boxtimes	is transmitted herewith.				
	b.		has been transmitted by the International Bureau.				
			Date of mailing (from form PCT/IB/308):				
	c.		is not required, as the application was searched by the United States International Searching Authority.				
	d.		will be transmitted promptly upon request.				
	e.		has been submitted by applicant on (Date)				
12. □ NOTE: 3			mation Disclosure Statement under 37 C.F.R. §§ 1.97 and 1.98:				
	"(b) .	An int	formation disclosure statement shall be considered by the Office if filed by the applicant ne of the following time periods:				
	•	,	nin three months of the date of entry of the national stage as set forth in § 1.491 in an all application.				
	a.		is transmitted herewith.				
Als	o tra	nsm	itted herewith is/are:				
			☐ Form PTO-1449 (PTO/SB/08A and 08B).				
			☐ Copies of citations listed.				
	b.		will be transmitted within THREE MONTHS of the date of submission of requirements under 35 U.S.C. § 371(c).				
	c.		was previously submitted by applicant on (Date)				
13. 🗆	An	assi	gnment document is transmitted herewith for recording.				
		A separate "COVER SHEET FOR ASSIGNMENT (DOCUMENT) ACCOMPANYING NEW PATENT APPLICATION" or FORM PTO 1595 is also attached.					
	_						

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14. K	Additional documents:
	a. Copy of request (PCT/RO/101)
	b. International Publication No
	i. Specification, claims and drawing
	ii.
	c. 🛛 Preliminary amendment (37 C.F.R. § 1.121)
	d. 🛛 Other
	AN UNEXECUTED DECLARATION
	A WRITTEN OPINION
15. 🛛	The above checked items are being transmitted
	a. 🛛 before 30 months from any claimed priority date.
	b. \square after 30 months.
16. 🗆	Certain requirements under 35 U.S.C. § 371 were previously submitted by the applicant on, namely:
	AUTHORIZATION TO CHARGE ADDITIONAL FEES
WARNING	3: Accurately count claims, especially multiple dependant claims, to avoid unexpected high charges
	if extra claims are authorized.
o a c a fo ir re	A written request may be submitted in an application that is an authorization to treat any concurrent refuture reply, requiring a petition for an extension of time under this paragraph for its timely submission, is incorporating a petition for extension of time for the appropriate length of time. An authorization to harge all required fees, fees under § 1.17, or all required extension of time fees will be treated as constructive petition for an extension of time in any concurrent or future reply requiring a petition or an extension of time under this paragraph for its timely submission. Submission of time in any concurrent eply requiring a petition for an extension of time in any concurrent eply requiring a petition for an extension of time under this paragraph for its timely submission." 37 is 1.136(a)(3).
re	Amounts of twenty-five dollars or less will not be returned unless specifically requested within a casonable time, nor will the payer be notified of such amounts; amounts over twenty-five dollars may be returned by check or, if requested, by credit to a deposit account." 37 C.F.R. § 1.26(a).
C h a si	the previous practice of holding applications abandoned if an authorization to charge fees under 37 c.F.R. § 1.16 has been provided instead of an authorization to charge fees under 37 c.F.R. § 1.492 has been changed. The Office amended 37 c.F.R. § 1.25(b), effective November 7, 2000, so that an authorization to charge fees under 37 c.F.R. § 1.16 in an international application entering the national rage under 35 U.S.C. § 371 is now accepted by the Office as an authorization to charge fees under 7 c.F.R. § 1.1492. Deposit Account 11-1755
⊠ Ple	DEDUSTL BUCCOBILL FIELFON
ma	ase charge, in the manner authorized above, the following additional fees that y be required by this paper and during the entire pendency of this application:
×	ase charge, in the manner authorized above, the following additional fees that y be required by this paper and during the entire pendency of this application: 37 C.F.R. § 1.492(a)(1), (2), (3), and (4) (filing fees)
×	ase charge, in the manner authorized above, the following additional fees that y be required by this paper and during the entire pendency of this application:
×	ase charge, in the manner authorized above, the following additional fees that y be required by this paper and during the entire pendency of this application: 37 C.F.R. § 1.492(a)(1), (2), (3), and (4) (filing fees) Because failure to pay the national fee within 30 months without extension (37 C.F.R. § 1.495(b)(2))

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NOTE:	must only be paid or these claims of set for response by the PTO in any	multiple dependent claims not paid on filing or on later presentation cancelled by amendment prior to the expiration of the time period notice of fee deficiency (37 C.F.R. § 1.492(d)), it might be best ditional claim fees, except possible when dealing with amendments
	☐ 37 C.F.R. § 1.17	(application processing fees)
	☐ 37 C.F.R. § 1.17(a)(1)-(5) (extension fees pursuant to § 1.136(a).
	☐ 37 C.F.R. § 1.18 (pursuant to 37 C.	(issue fee at or before mailing of Notice of Allowance, F.R. § 1.311(b))
NOTE:	may be filed in an individual application general authorizations to pay fees at to the mailing of a notice of allowand fee and will not be given effect to a the issue fee, should submit a new a current PTOL-85B form. Where no reabandoned notwithstanding the preset to pay the issue fee that were submits made to pay the issue fee but an issue fee transmittal form (currently Pin reply to a notice of allowance, and to charge the issue fee to any depot the mailing of the notice of allowance, of the correct issue fee. § 1.311(b). Fed. Reg. 54603-54683, at 54646 at 37 C.F.R. § 1.28(b) requires "Notification of 37 C.F.R. § 1.28(b): (a) notification than a small entity" and (b) no notification.	ntion of any change in loss of entitlement to small entity status must to paying, or at the time of paying issue fee." From the wording n of change of status must be made even if the fee is paid as "other lication is required if the change is to another small entity.
	and/or filing an Er	2(e) and (f) (surcharge fees for filing the declaration nglish translation of an International Application later after the priority date).
		Sullyn-
		SIGNATURE OF PRACTITIONER
Reg. No.	: 33,529	EDWARD M. KRIEGSMAN
Tel. No.:	(508) 879-3500	(type or print name of practitioner) KRIEGSMAN & KRIEGSMAN 665 FRANKLIN STREET
Custome	r No.: 23685	P.O. Address
	23003	FRAMINGHAM, MA 01702